

## **REMARKS**

In the Official Action, the Examiner rejected claims 1-24. Reconsideration of above-referenced application is respectfully requested.

### **Rejections Under 35 U.S.C. § 103**

The Examiner rejected claims 1-24 under 35 U.S.C. § 103(a) as being unpatentable over Soukal (U.S. Pat. No. 6,035,328) in view of Berkowitz et al. (U.S. Pat. No. 5,392,400) and Budd et al. (U.S. Pat. No. 5,662,108). Specifically, the Examiner stated:

Soukal discloses a medical therapeutic and/or diagnostic system with a central server 8 and a plurality of operating means (4, 6, 9, 11) at various locations. The system provides for exchange of control and display data (column 1, lines 12-18, and claim 1). Soukal does not expressly disclose data replicating and the cardiac catheterization procedure. Berkowitz et al. teaches that it is known to provide a collaborative computing method and system wherein output data from and input data for an application program are shared among all of the computers and the output from the application program is intercepted and then replicated on each of the computers' displays as set forth in the abstract. A replicating mechanism provides for sharing of contents (i.e. data) from viewing at participating workstations (column 6, lines 5-26) in real-time (column 3, lines 14-17). Budd et al. teaches that it is known to perform a cardiac catheterization procedure as set forth in the abstract. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the medical data processing system of Soukal with a replicating mechanism, as taught by Berkowitz et al, in order to provide efficient real-time access to display contents at the remote locations, and to use the system in combination with a cardiac catheterization procedure and system, as taught by Budd et al, because this merely involves combining elements of art recognized suitability for an intended purpose. See MPEP § 2144.07. The resulting system would inherently perform the claimed method.

Applicants respectfully traverse this rejection. The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion support the combination. *ACS*

*Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes all of the claimed elements, but also present a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988).

The present application is directed to a distributed multi-user system for real time data access during cardiology procedures. Page 1, lines 10-11. More specifically, the present application is directed to an interactive computer network which can be used to simultaneously display and manipulate data from a cardiology procedure on a plurality of devices and at a plurality of locations. Page 1, lines 11-14. As stated in the background of the present application, an electrophysiology study (EPS) involves the pacing and recording of electrical signals within localized areas of the heart. Page 2, lines 6-7. To perform such procedures as an EPS, a cardiac catheterization lab is provided in which multiple clinicians can diagnose and treat heart conditions. Page 3, lines 27-29. It would be advantageous for clinicians to be able to interact with and manipulate the clinical data *simultaneously* during an EP procedure. Page 3, lines 30-32.

Current techniques to accommodate the complex workflow in a cardiac catheterization lab, such as the workflow required during an EP procedure, are insufficient to meet these needs. Page

4, lines 8-9. Prior techniques of decentralizing study data by publishing from a central location, such as a server, to multiple remote locations residing within the cardiac catheterization labs or throughout a medical institution only provide for the distribution of data after all of the data is entered. Page 9, lines 20-23. Conversely, by implementing the presently described technique using merge replication, the electrophysiology data can be collected, replicated and simultaneously displayed *during* the cardiac catheterization procedure.

Accordingly, claims 1 and 13 each recite, in relevant part, a method of accessing a study record taken *during* a cardiac catheterization procedure, comprising the acts of transmitting data from a catheter to a data collection device, transmitting the data from the data collection device to a central publisher, replicating the data, transmitting the replicated data from the central publisher to a plurality of client workstations, and *simultaneously* displaying the data on the plurality of client workstations.

The Soukal reference does *not* disclose a method of accessing data during a cardiac catheterization procedure, much less replicating, transmitting and simultaneously displaying the data during the procedure. Conversely, the Soukal reference discloses “a medical therapeutic and/or diagnostic system with at least one operating means with allocated computing means and control means communicating therewith for controlling the operation of the system.” Col. 1, lines 6-10. “Each operating means has computing means wherein a special software is filed which is directed to the respective medical-technical application for which it has been developed.” Col. 1, lines 18-21. “This special software is provided in each of the operating means, since each of the operating means works quasi-‘independently.’” Col. 1, lines 21-23. “Besides the inflexibility of this system, a further disadvantage is that to modify the stored software, the modification must be recorded individually for each operating means, which is cumbersome and time-consuming.” Col. 1, lines

24-27. “In contrast to known systems, at least part of the operating and/or processing data previously stored in the computing unit of the operating means, i.e., the system’s specific technical software, is not stored there anymore, but rather is only implemented in the control means, which delivers the software to the operating means only as needed, such as in the startup of the operating means or the like.” Col. 1, lines 40-47.

Thus, the Soukal reference is directed to a system that permits the sharing of the *operating software* as opposed to the *data acquired* during a test procedure. The Soukal reference is not directed to the sharing of test data, at all, but rather to the sharing of operating software. The Examiner again characterizes the Soukal system as “a medical data processing system” that “provides for exchange of control and display data.” Office Action, page 3. This is a mischaracterization of the Soukal system. In contrast, the Soukal reference discloses a mechanism (control unit 8) for sharing the software necessary to conduct the test procedure, whether it be internally (at operating units 4 and 6) or externally (at operating units 9 or 11). This point is specifically addressed by the Board in the Decision on Appeal, wherein the Board stated:

Concerning this matter, we observe that Soukal describes a medical therapeutic and/or diagnostic system including at least one operating means including computing means allocated thereto, and a control means communicating therewith for controlling the operation. Exemplary therapeutic and/or diagnostic systems described as prior art in Soukal (column 1, lines 13-18) include x-ray and shock wave systems. Soukal (column 1, lines 40-47) teaches that: at least a part of the operating and/or processing data previously stored in the computing unit of the operating means, i.e., the system’s specific technical software, is not stored there anymore, but rather is only implemented in the control means, which delivers the software to the operating means only as needed, such as in the startup of the operating means or the like. In the drawing figure, Soukal depicts an arrangement employing a number of operating units, including intranet connected units and external operating means (11) that require use of a public network, i.e., the Internet, for connection. At column 3, lines 29-34, Soukal further provides that: [t]he communication between the operating units 4

and 6 and the control unit 8 ensues via an HTTP protocol, so that the control unit 8 acts as an HTTP-server, which places the necessary operating and/or processing data, i.e., the respective software, at the operating unit side, at one's disposal as needed. From the above passages, it is clear that Soukal is concerned with software exchange and storage for use in the operating means as argued by appellants (brief, page 7, first full paragraph), not data acquired during a test procedure. The examiner refers to column 1, lines 54-56 of Soukal for a teaching of data transmission. However, as evident from the passages reproduced above, Soukal use the term "exchange of data" as that term relates to operating or processing data (software).

For this reason alone, it is clear that the Examiner is misapplying the teachings of the Soukal reference. As explicitly stated by the Board, "[f]rom the above passages, it is clear that Soukal is concerned with software exchange and storage for use in the operating means as argued by appellants (brief, page 7, first full paragraph), not data acquired during a test procedure." Applicants respectfully submit that this issue has been decided by the Board in favor of Applicants. Thus, the Examiner's continued reliance on the Soukal reference as disclosing a medical data processing system that provides for exchange of control and display data is in direct conflict with the Board's finding. For this reason alone, Applicants respectfully submit that the Examiner has failed to meet his burden of establishing a *prima facie* case of obviousness.

Further, as recognized by the Examiner, even if the Soukal reference did disclose a system for sharing test data during a procedure, the Soukal reference does not disclose *replicating* the data, *transmitting the replicated data* from a central publisher to a plurality of client workstations or *simultaneously* displaying the data on the plurality of client workstations, as recited in the present claims. To address this deficiency, the Examiner seems to be relying on the Berkowitz reference as teaching these features. The Examiner also appears to suggest that the recited features are inherent in the cited combination. Further, the Examiner cites the Budd reference as teaching a cardiac catheterization procedure. Applicants respectfully submit that the cited combination does

not disclose each of the recited features nor is there any suggestion to combine the references in the manner recited by the present claims.

The Berkowitz reference is directed to collaborative computing. The Examiner directs Applicants to col. 6, lines 5-26 of the Berkowitz reference as disclosing replicating the data, transmitting the replicated data from a central publisher to a plurality of client workstations and simultaneously displaying the data on the plurality of client workstations. Applicants respectfully submit that among other deficiencies, there is nothing in the Berkowitz reference to suggest that replicated data is transmitted from a central publisher to a plurality of client workstations. Further, as discussed above, the Soukal reference is directed to a system that permits the sharing of the *operating software* as opposed to the *data acquired* during a test procedure. The Soukal reference is not directed to the sharing of test data, at all, but rather to the sharing of operating software. Accordingly, there is absolutely no motivation or suggestion in the Soukal reference to modify any of the data display features that may be present in the Soukal reference in any way, much less in a way that would allow for the collaborative computing techniques disclosed by Berkowitz. Accordingly, even if cited combination did disclose each of the recited features, Applicants respectfully submit that one skilled in the art would not be motivated to combine the references in the manner recited in the present claims. For these additional reasons, Applicants respectfully submit that the present claims are not rendered obvious by the cited combination.

Further, while the Examiner maintains that the cited combination discloses all of the recited features, the Examiner further submits that the replicating feature recited in the present claims is inherent in the Soukal-Berkowitz combination. Applicants traverse this assertion. If the Examiner relies on a theory of inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so

recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999) (Emphasis Added). The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *Id.* In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner, in presenting the inherency argument, bears the evidentiary burden and must adequately satisfy this burden. *See id.* Regarding functional limitations, the Examiner must evaluate and consider the functional limitation, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *See* M.P.E.P. § 2173.05(g); *In re Swinehart*, 169 U.S.P.Q. 226, 229 (C.C.P.A. 1971); *In re Schreiber*, 44 U.S.P.Q.2d 1429, 1432 (Fed. Cir. 1997). If the Examiner believes the functional limitation to be inherent in the cited reference, then the Examiner "must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art." *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Inter. 1986).

As discussed above, Applicants maintain that the cited combination does not disclose each of the recited features and that there is simply no suggestion to combine these features in the manner recited in the present claims. Applicants further submit that even if there was a suggestion to combine the references, the recited features would not be inherent. Specifically, Applicants respectfully submit that the replication, transmission and simultaneous display of data during a cardiac catheterization procedure is not inherent, nor does it necessarily follow from the system disclosed in the hypothetical Soukal-Berkowitz combination.

Prior techniques of decentralizing study data by publishing from a central location, *such as a server*, to multiple remote locations residing within the cardiac catheterization labs or throughout a medical institution are insufficient, because they only provide for sharing data *after* all of the data is entered, as explicitly discussed in the present application. Page 9, lines 20-23. Even if the system disclosed in the Soukal reference could be implemented during a cardiac catheterization procedure, and even if system were implemented for data distribution, it is clear that at best, the control unit (HTTP-server) 8 would only allow for data distribution *after* the procedure, and not *during* the procedure, as recited in the present claims. Applicants are unaware of how the Soukal reference could be modified in view of Berkowitz and are unaware of how the modification would provide real time data sharing. Inherency cannot be established by probabilities or possibilities -- the mere fact that a certain thing may result from a given set of circumstances is not sufficient. *In re Olerich and Divigard*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Because it is clear that replication, transmission and simultaneous display of data during a cardiac catheterization procedure does not *necessarily* flow from the teachings of the Soukal-Berkowitz combination, these elements cannot possibly be inherent.

Because the Examiner has not met this required burden of proof, the Examiner has failed to make out a *prima facie* case of inherency. Further, in the Response to Arguments section of the Office Action, the Examiner states that “[t]he arguments regarding inherency appear to be based on features as set forth in the specification rather than the full scope of claim 1.” Applicants respectfully traverse this assertion. As set forth in detail above, the Examiner seems to be suggesting that the hypothetical Soukal-Berkowitz system, as described by the Examiner, would inherently perform the elements recited in the present claims. More specifically, the Examiner’s position appears to be that the hypothetical Soukal-Berkowitz system would inherently provide a method of accessing a study record taken *during* a cardiac catheterization procedure, comprising



the acts of transmitting data from a catheter to a data collection device, transmitting the data from the data collection device to a central publisher, replicating the data, transmitting the replicated data from the central publisher to a plurality of client workstations, and *simultaneously* displaying the data on the plurality of client workstations. Applicants maintain that these steps are not inherent in the hypothetical Soukal-Berkowitz system. Further Applicant's are unclear as to why the Examiner suggested that Applicants are relying on features in the specification, rather than elements recited in the claims, as it is clear that Applicants are indeed basing all arguments, including those relating to inherency, on the features explicitly recited in the claims.

Further, as clearly appreciated by the Examiner, while the Budd et al. reference may disclose a cardiac catheterization procedure, it does not disclose replicating the data, transmitting the replicated data from a central publisher to a plurality of client workstations or simultaneously displaying the data on the plurality of client workstations. Thus, the Budd reference fails to cure the deficiencies described above with respect to the Soukal-Berkowitz combination. Therefore, the cited combination does not even disclose all of the claimed elements, much less provide any suggestion to combine these disparate teachings to render the claimed subject matter obvious. Still further, the recited features are not inherent if the hypothetical combination.

In view of the remarks set forth above, Applicants respectfully submit that the subject matter of claims 1-24 is not rendered obvious by the cited combination. Accordingly, Applicants request withdrawal of the Examiner's rejection and allowance of claims 1-24.

### **Conclusion**

In view of the remarks and amendments set forth above, Applicants respectfully request reconsideration of the Examiner's rejections and allowance of claims 1-24. If the Examiner

believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: August 3, 2005

A handwritten signature in black ink, appearing to read 'R. A. Manware', is written over a horizontal line.

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